

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND :
PHARMACEUTICALS, WARNER- :
LAMBERT COMPANY, WARNER- :
LAMBERT COMPANY, LLC, and :
WARNER-LAMBERT EXPORT, LTD., :
:
Plaintiffs, :
:
v. : Civil Action No. 03-209-JJF
: (Consolidated)
RANBAXY LABORATORIES LIMITED :
and RANBAXY PHARMACEUTICALS, :
INC., :
:
Defendants. :
:

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Attorneys for Defendants.

MEMORANDUM OPINION

December 20, 2005
Wilmington, Delaware

Joseph J. Farnan, Jr.
Farnan, District Judge.

Pending before the Court are two post-trial motions filed by Plaintiffs, Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company, LLC and Warner-Lambert Export, Ltd. (collectively, "Pfizer"): (1) Pfizer's Rule 37(c) (1) Motion To Exclude Previously Undisclosed Expert Opinions And Exhibits (D.I. 314), and (2) Pfizer's Motion To Exclude The Austrian Patent Office Decision Under Federal Rules Of Evidence 402 and 403 (D.I. 319). Answer Briefs to the Motions have been filed by Defendants, Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Incorporated (collectively "Ranbaxy"). For the reasons discussed, the Court will grant-in-part and deny-in-part Pfizer's Rule 37(c) (1) Motion and deny Pfizer's Motion To Exclude The Austrian Patent Office Decision. In addition, the Court will sustain-in-part and overrule-in-part Pfizer's post-trial objections to Dr. Butler's papers.

DISCUSSION

I. Pfizer's Rule 37(c) (1) Motion

A. The Parties' Contentions

By its Motion, Pfizer requests the Court to exclude two expert opinions offered by Ranbaxy at trial which Pfizer contends were not previously disclosed, and any findings of fact and conclusion of law offered by Ranbaxy in their post-trial briefs which rely upon these allegedly undisclosed opinions.

Specifically, Pfizer seeks to exclude the opinion of Dr. Cooperman regarding the use of nuclear magnetic resonance spectra to determine the alleged impurity of racemic atorvastatin lactone compounds and the opinion of Dr. Bowman regarding an econometric regression analysis that he had performed.

In response, Ranbaxy contends that Dr. Cooperman's expert report indicated that he "expect[ed] to testify [concerning] rebuttal testimony to any testimony offered by witnesses for Pfizer." D.I. 323, Exh. B, DTX 409, ¶ 10. Ranbaxy further contends that Dr. Cooperman's trial testimony concerning the use of nuclear magnetic resonance ("NMR") spectra to determine the alleged impurity of racemic atorvastatin lactone compounds was consistent with the opinions in his expert report that the data provided in the '995 patent was unreliable. Procedurally, Ranbaxy contends that it complied with the provisions of the Pretrial Order which required "each party to provide the other party of a list of witnesses that it intends to call and a list of the non-demonstrative and demonstrative exhibits that the party intends to use with the witness by 6pm two calendar days before the witness is expected to testify." (D.I. 219 at 5, ¶ C). In addition, Ranbaxy points out that Pfizer's expert, Dr. Roush, testified after Dr. Cooperman, and thus, Ranbaxy contends that Pfizer had ample opportunity to prepare for cross-examination of Dr. Cooperman and rebut his testimony through the

testimony of Dr. Roush.

As for Dr. Bowman's analysis, Ranbaxy contends that it complied with its disclosure obligations by providing Pfizer with the exhibits in question well before trial. Ranbaxy also contends that Pfizer has not demonstrated any prejudice as a result of Dr. Bowman's testimony, and therefore, exclusion of his testimony and the related exhibits is not warranted.

B. Analysis

Pursuant to Federal Rule of Evidence 26(a)(2)(B), an expert report "shall contain a complete statement of all opinions to be expressed and the basis and reasons therefor." Failure to disclose information required by this Rule may result in the exclusion of evidence based on that information, unless the failure to disclose is harmless. Fed. R. Civ. P. 37(c)(1). The determination of whether to exclude evidence is committed to the Court's discretion. In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 749 (3d Cir. 1994) (on a motion to exclude proffered expert testimony, the trial court's inquiry is a flexible one, and its decision to admit or exclude expert testimony is reviewed under an "abuse of discretion" standard) (internal citations omitted).

1. Dr. Cooperman's testimony and related exhibits

At trial, Pfizer objected to the testimony of Dr. Cooperman to the extent it pertained to impurities of racemic atorvastatin lactone compounds based on NMR spectra. The Court reserved

ruling on Pfizer's objection but stated that "[i]f it's not fairly noticed in the report, it gets excluded; if it's in the report, the objection gets overruled." Tr. 1364:20-23. The Court has reviewed Dr. Cooperman's report and finds no mention of alleged impurities of racemic atorvastatin lactone compounds or the use of NMR to measure the impurity content of compounds. At his deposition, Dr. Cooperman testified that he had performed preliminary calculations to determine the effect of the 3% S-isomer contamination of atorvastatin lactone (the R-isomer) in CSI 107. These calculations were later provided to Pfizer, and Dr. Cooperman was made available for second deposition. At no time during his first or second deposition did Dr. Cooperman mention the use of NMR to measure impurities of racemic atorvastatin lactone compounds. Ranbaxy has not provided an explanation for its failure to fulfil its disclosure obligations under Rule 26, and Pfizer was denied the opportunity to prepare for rebuttal to Dr. Cooperman's testimony.¹ Accordingly, the

¹ Ranbaxy contends that Dr. Cooperman's testimony was based on the "newly created" justification for disregarding certain data based on impurities offered by Dr. Roth at trial. Ranbaxy has not indicated to the Court that it objected to Dr. Roth's testimony at trial, and the Court has been unable to locate any such objection in the record. Further, Ranbaxy introduced DTX 3325A during the testimony of Dr. Roth, which suggests to the Court that Ranbaxy was on notice as to Dr. Roth's testimony. However, to the extent that Pfizer seeks to exclude DTX 3325A from the trial exhibits, the Court declines to do so. This exhibit was not objected to when it was introduced through Dr. Roth, and the Court has been unable to locate any trial objection by Pfizer to this exhibit, although Pfizer did timely

Court will exclude Dr. Cooperman's testimony concerning the use of NMR spectra to assess impurities in racemic atorvastatin lactone, and any findings of fact and conclusions of law submitted by Ranbaxy based on this testimony.

2. Dr. Bowman's testimony and related exhibits

As for the testimony and exhibits regarding the regression analysis of Dr. Bowman, the Court finds that Ranbaxy complied with its disclosure obligations, and therefore, this testimony and the related exhibits will not be excluded from the trial record. Pfizer was on notice that Dr. Bowman would be performing a new regression analysis if errors were found in the analysis. The corrected analysis was produced to Pfizer during Dr. Rao's deposition in August 2004 as DTX 484 and again in October 2004 as DTX 868. Both of these exhibits were also listed in the Pretrial Order. As for DTX 3477, which Pfizer also seeks to exclude, the Court observes that this exhibit is merely a summary of DTX 868 and contains no new information. Because no new materials were presented to Pfizer on the eve of the witness's testimony and Pfizer had notice well before trial of the exhibits in question, the Court concludes that Ranbaxy has complied with its duties to disclose and supplement insofar as the Bowman materials are

object to Dr. Cooperman's testimony. Accordingly, the Court will allow the exhibit into evidence to the extent it applied to Dr. Roth's testimony, but strike any testimony from Dr. Cooperman regarding the exhibit.

concerned. Accordingly, the Court will deny Pfizer's motion to exclude Dr. Bowman's trial testimony and related exhibits.

3. Dr. Butler's papers

In its Supplemental Findings of Fact and Supplemental Conclusion of Law, Pfizer moves the Court to exclude certain documents that were not proffered at trial, but were included in Ranbaxy's Findings of Fact.² Pfizer contends that these documents should be excluded from the trial record under Federal Rule of Evidence 613(b). Pfizer contends that Ranbaxy is using these documents as prior inconsistent statements to impeach Dr. Daignault, and therefore, Dr. Daignault should have had the opportunity to be presented with these documents.

In response, Ranbaxy contends that the Court should not exclude this evidence. Ranbaxy contends that the manuscript request forms in question are not evidence of any prior inconsistent statement by Dr. Daignault, and that they are proper rebuttal evidence. Ranbaxy also contends that Dr. Butler's letter and manuscript review forms are part of the trial record contained in Defendant's Exhibit 293.

Although Ranbaxy contends that the documents in question are not evidence of prior inconsistent statements, it is clear to the Court that they are being used by Ranbaxy in this manner.

² Although the Court will address these matters, the Court notes that the objections should have been lodged separately and not contained within the body of Pfizer's filings.

Although they may not be prior inconsistent statements per se, Ranbaxy urges the Court to view these documents as indicative of Dr. Daignault's awareness and understanding of the '080 patent in an effort to undermine his trial testimony to the contrary. To this extent, the Court concludes that the documents should have been presented to Dr. Daignault under Rule 613(b). Accordingly, to the extent that the documents can be considered prior inconsistent statements, the Court will exclude them from the trial record.

To the extent these documents can be construed differently, the Court will allow their admission into evidence but afford them limited weight. Dr. Daignault was not given the opportunity to discuss the documents, and the documents were raised by way of post-trial briefing.

II. Pfizer's Motion To Exclude The Australian Patent Office Decision

A. Parties' Contentions

By its Motion, Pfizer requests the Court to exclude the Australian Patent Office decision relied upon by Ranbaxy in its Opposition Post-Trial Brief. Pfizer contends that the decision of the Nullity Division of the Austrian Patent Office is non-final and irrelevant to the validity of claim 6 of the '995 patent over prior art under United States law.

In response, Ranbaxy contends that this evidence should not be stricken from the record, because it has at least some

relevance to this litigation under Federal Rule of Evidence 402. Ranbaxy also contends that Pfizer has not demonstrated unfair prejudice, confusion, undue delay or that the evidence is cumulative under Federal Rule of Civil Procedure 403.

B. Analysis

Reviewing the challenged evidence in light of the standards for admissibility, the Court concludes that the evidence offered by Ranbaxy should not be stricken. The Federal Circuit does not endorse the per se exclusion of evidence related to foreign patent prosecutions. Rather, the Federal Circuit has recognized that such matters may be relevant in certain circumstances. See e.g. Tanabe Seiyaku Co. v. U.S. Int'l Trade Comm'n, 109 F.3d 726, 733 (Fed. Cir. 1997); Caterpillar Tractor Co. v. Berco, S.p.A., 714 F.2d 1110, 1116 (Fed. Cir. 1983). Indeed, this Court has also recognized the "limited relevance" of proceedings adjudicating patent rights in foreign jurisdictions. See Bayer AG v. Sony Electronics, Inc., 229 F. Supp. 2d 332, 369 (D. Del. 2002). Because the Court cannot conclude that this evidence is entirely irrelevant, and Pfizer has not advanced any grounds under Rule 403 justifying its exclusion, the Court will admit the evidence and address Pfizer's concerns in terms of the weight to be afforded this evidence. Accordingly, Pfizer's Motion To Exclude The Austrian Patent Office Decision will be denied.

CONCLUSION

For the reasons discussed, Pfizer's Rule 37(c)(1) Motion To Exclude Previously Undisclosed Expert Opinions And Exhibits will be granted as it pertains to Dr. Cooperman's testimony and the findings of fact and conclusions of law based on that testimony, and denied as it pertains to the testimony of Dr. Bowman and the exhibits, findings of fact and conclusions of law related to his testimony. Pfizer's Objections to Dr. Butler's papers contained in the post-trial briefing will be sustained to the extent that the papers are prior inconsistent statements and overruled to the extent they can be considered other impeachment evidence.

An appropriate Order will be entered.